Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

Mr. Henry Darwin
Chief of Operations
Mail Code 1101A
United States Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, D.C. 20460

via Certified Mail and electronic mail to Darwin.Henry@epa.gov

RE: Denka Performance Elastomer
Chloroprene PBPK Model Update and Response to Holloman Letter of 11/1/18

Dear Mr. Darwin:

On behalf of Denka Performance Elastomer LLC (DPE), I write to follow up on our October 12, 2018 letter to you asking that EPA stay its consideration of DPE's Request for Reconsideration (RFR #17002A) regarding chloroprene. As we explained in that letter, DPE has been working with EPA's Office of Research and Development (ORD) to develop a physiologically-based pharmacokinetic (PBPK) model that will likely resolve several key issues in the RFR.

The purpose of this letter is to update EPA on the considerable work that has been done on the PBPK modeling effort and to renew our request in the October 12th letter that EPA stay its review of the RFR until this work can be completed. As discussed further below, we also request the elimination of the February 1, 2019 deadline that EPA's Office of Environmental Information (OEI) has set for the submittal of additional information regarding chloroprene. As explained below, because of the need to conduct additional laboratory work requested by ORD, the PBPK model will not be available by that time.

Background

On July 24, 2018, DPE submitted a Request for Reconsideration (RFR #17002A) to amend and update the Toxicological Review of Chloroprene published by EPA's Integrated Risk Information System (IRIS) in 2010. As described below, DPE and EPA shortly thereafter agreed to work collaboratively on a PBPK model for chloroprene metabolism that will likely have significant impact on key IRIS values and the RFR. Because of this, DPE felt it was inappropriate for EPA to continue review of the RFR and sent a written request to you on October 12, 2018 asking that EPA stay its review of the RFR until the PBPK model was complete.

Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

Shortly thereafter, we received a letter from Vincia Holloman of the Office of Environmental Information (OEI) dated November 1, 2018. This letter was written in response to DPE's RFR and requested that DPE provide any further supporting information by February 1, 2019. The letter makes no mention of DPE's request to stay review of the RFR.

PBPK Model Developments Since July 19

On July 19, 2018, representatives of DPE and the Ramboll Group, DPE's toxicology consultants, met with officials from EPA's National Center for Environmental Assessment (NCEA) in Research Triangle Park, N.C. (RTP), to begin the process of working collaboratively on the PBPK model. On August 6, Ramboll provided Dr. Paul Schlosser of NCEA the computer code to Ramboll's updated PBPK model.

Dr. Harvey Clewell and others with Ramboll have since been in regular communication with Dr. Schlosser and his team regarding the evaluation of pharmacokinetic parameters and calculation methods in the PBPK model. Dr. Schlosser and his staff have reviewed the model code and can get it to run. However, Dr. Schlosser requested that the metabolism parameters in the model (which are based on a previously published study) be revised using a mass-transport coefficient for gas to liquid transfer. This is an additional experimental parameter that was estimated but not measured for the previous study.).

Ramboll did a series of sensitivity studies to determine the potential impact this parameter may have on the model predictions that would be utilized in a risk assessment. Although the sensitivity studies showed that the parameter's impact on a risk assessment would be minimal, Dr. Schlosser has requested laboratory verification of the chloroprene mass-transport coefficient and we have been working to provide it.

As the following chronology will show, DPE and Ramboll have been working assiduously on the PBPK issues and are keeping the PBPK model development on track. Dr. Schlosser requested the additional laboratory work in September 2018. DPE and Ramboll began working together to develop a protocol to measure this parameter, completing a workable first draft by early October, 2018. Once that was complete, we had to find a laboratory that could complete the protocol. This is specialized laboratory work and very few laboratories can do it, and even fewer have experience with chloroprene. After several false starts, DPE identified a laboratory that could do it in early November.

The laboratory, Teklab, Inc., set to work adapting our protocol to their equipment and abilities. By December, Teklab sent us their proposed protocol. Dr. Clewell forwarded it to Dr. Schlosser for review. On December 18, Dr. Schlosser provided his comments. Ramboll had to perform additional

Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

research to address Dr. Schlosser's comments, and then used that research to amend Teklab's protocol.

On January 7, we provided the amended protocol to Teklab. On January 9, Teklab determined that they could complete the amended protocol but only after purchasing or renting certain new equipment, at least one piece of which may not be available for 6 weeks.

Next Steps with the PBPK Model

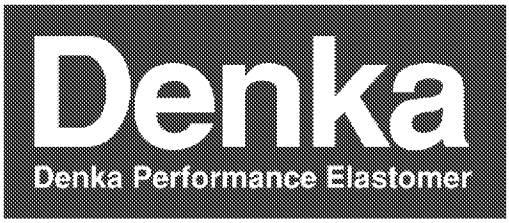
Once Teklab has the necessary equipment, it will take them at least 2 weeks to conduct the lab work and generate the data requested by ORD. Ramboll will then require time to synthesize Teklab's data into a working, scientifically defensible parameter that can be submitted to Dr. Schlosser for review. Once we obtain his approval, the parameter will have to be used in the model and the results submitted to EPA for review. Although it is difficult to be precise with the schedule of upcoming work, we are optimistic about the completion of the PBPK development in the next several months.

As noted above, we believe that the completion of the PBPK model will have a material impact on DPE's RFR, and will provide EPA with valuable new information that will allow the Inhalation Unit Risk (IUR) for chloroprene to be updated based the best available science. However, for the reasons discussed above, the PBPK model will not be completed by the February 1 deadline set forth in OEI's November 1st letter. Therefore, DPE requests that this deadline be eliminated. We also reiterate our request that EPA stay its consideration of the RFR until the PBPK modeling effort can be completed.

Thank you for EPA's continued collaboration on this matter and for prioritizing the expedited review of the chloroprene model. We will provide further updates as events warrant and would be pleased to meet with you or your staff at any time to provide further information of these issues.

Yours sincerely,

Patrick A. Walsh, CIH
Safety, Health, and Environmental Manager
Denka Performance Elastomer LLC



Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

cc: All Via Email Only:
Ms Vincia Holloman, Director, Enterprise Quality Management Division, OEI
Mr. Bill Wehrum, Assistant Administrator
Mr. Vaughn Noga, Acting Assistant Administrator
Ms. Brittany Bolen, Associate Administrator
Dr. Tina Bahadori, ScD ORD/NCEA Director
Mr. David Gray, EPA Region 6 Director of External Affairs
Ms. Anne Idsal, JD, Region 6 Administrator
Dr. John Vandenberg, ORD/NCEA RTP Division Director
Dr. Kristina Thayer, ORD/NCEA IRIS Division Director
Mr. Kevin Kirby, Enterprise Data Architect, OEI
Dr. Chuck Carr Brown, Secretary, LDEQ
Lori E. Sanders, DowDuPont
Robert E. Holden, Jones Walker
Elise M. Henry, Jones Walker